UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

In re: PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	)	MDL No. 1456
	)	Civil Action No. 01-12257-PBS
THIS DOCUMENT RELATES TO:	)	Subcategory No. 06-11337-PBS
United States of America ex rel. Ven-a-Care of the Florida Keys, Inc., v. Boehringer Ingelheim Corp., et al., Civil Action No. 07-10248-PBS; and	)	Hon. Patti B. Saris
United States of America ex rel. Ven-a-Care of the Florida Keys, Inc. v. Dey L.P., et al., C.A. No. 05-11084.	)	

MEMORANDUM OF LAW IN SUPPORT OF UNITED STATES' MOTION TO CONSOLIDATE CASES FOR TRIAL

INTRODUCTION

The United States' allegations against defendants Dey, Inc., Dey L.P., Inc., and Dey L.P. ("Dey") and defendants Boehringer Ingelheim Corporation ("BIC"), Boehringer Ingelheim Pharmaceuticals, Inc. ("BIPI"), Roxane Laboratories, Inc., and Roxane Laboratories, Inc. n/k/a Boehringer Ingelheim Roxane, Inc. (collectively, "Roxane" or the "Roxane Defendants") are alike, and trial will be based in no small measure on a common factual record that will involve common witnesses, as well as a calculation of damages necessarily based on both defendants' reported prices for the drug responsible for the largest share of damages. The cases should be consolidated for trial because doing so will promote judicial economy, and minimize the expense and delay (to the Court, the

parties, and witnesses) of separately trying two complicated cases based on similar legal theories and parallel factual allegations. The defendants cannot show that consolidation will cause them demonstrable prejudice. *See* Fed. R. Civ. P. 42(a).

Both cases allege that Dey and the Roxane Defendants, respectively, violated the False Claims Act by reporting false prices to third-party pricing compendia with the intended purpose of increasing Medicare and Medicaid reimbursement to healthcare providers who purchased the defendants' products. The cases rest upon the same legal theories and involve common issues of fact and law including (among others): the falsity of the reported prices; the reimbursement methodologies used by the Medicare and Medicaid programs; and whether those programs approved the defendants' price reporting conduct.

In addition, the majority of the damages in both cases relate to inflated Medicare reimbursement for one drug, Ipratropium Bromide, which was marketed and sold by both Dey and Roxane and for which Medicare set a common allowed reimbursement amount based on both companies' reported prices. More specifically, almost all of the claims for reimbursement for this drug were paid based on the median of a group of reported prices dominated by Dey's and Roxane's reported prices. Consolidation, therefore, is particularly appropriate here because calculating Medicare damages for Ipratropium Bromide against either Dey or Roxane involves the same Medicare pricing array documents and witnesses, and requires analysis of the increase in Medicare spending

caused by the joint impact of both companies' fraudulent price reporting on Medicare's allowed reimbursement amount.

I. FACTUAL BACKGROUND

A. The Case Against the Roxane Defendants

The Roxane Defendants reported false prices for nine multi-source drugs, consisting of 35 National Drug Codes ("NDCs"): Azathioprine, Diclofenac Sodium, Furosemide, Hydromorphone, Ipratropium Bromide, Oramorph SR, Roxicodone, Roxanol and Sodium Polystyrene Sulfonate. For all drugs other than Ipratropium Bromide, the claims run from February 15, 1999. For Ipratropium Bromide, the claims run from the date of the products' launch, the earliest of which occurred in June 1996. The United States has calculated Medicaid damages for all nine Roxane drugs through the first quarter of 2008[1] and Medicare damages for Ipratropium Bromide through 2003.

B. The Case Against Dey

Dey reported false prices for three groups of multi-source inhalation therapy drugs, consisting of 26 NDCs: Albuterol Sulfate, Cromolyn Sodium and Ipratropium Bromide. Of the Albuterol Sulfate products, the most significant product (Albuterol Sulfate Inhalation Solution 0.083%, unit dose) was launched in 1992. Dey launched other Albuterol Sulfate products in 1996, and launched its Cromolyn Sodium products in 1994. Dey launched its Ipratropium Bromide products in January and August 1997 (following

[1] For certain states, the United States has not calculated Medicaid damages for the first quarter of 2008 due to lack of data.

the launch of Roxane's Ipratropium Bromide products in June 1996).[2] The United States has calculated Medicaid damages for all three Dey drugs through the first quarter of 2008,[3] and Medicare damages for Albuterol Sulfate and Ipratropium Bromide through 2003.

C. The Cases Involve Parallel Allegations About the Defendants' Conduct

The United States brings three identical causes of action against Dey and the Roxane Defendants: 1) Count I in both cases asserts claims for violating the False Claims Act, 31 U.S.C. § 3729(a)(1), by presenting or causing to be presented false claims to the United States; Count II in both cases asserts claims for violating the False Claims Act, 31 U.S.C. § 3729(a)(2), by making or using false records and statements to cause false claims to be made; and Count III in both cases asserts claims for unjust enrichment.[4] In each case, the United States expects to prove that defendants intentionally created and maintained spreads between reported Average Wholesale Prices ("AWPs") and actual acquisition costs for the purpose of inducing pharmacies and other providers to purchase their products. The United States also intends to prove that Dey and the Roxane

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[2] The original NDCs of the three Dey products were superceded in later years when Dey introduced newly-packaged versions of the drugs with new NDC numbers.

[3] As in the case of Roxane, for certain states, the United States has not calculated Medicaid damages for the first quarter of 2008 due to lack of data.

[4] The United States has filed stipulations in both the Dey and Roxane cases dismissing the Common Law Fraud claims. Master docket ("MD") #6163, Sub. #227; MD #6164, Sub. #229.

Defendants trained their respective sales forces to market the spread on the companies' products, and that they in fact marketed the spread.

The majority of the damages in both the Dey and Roxane cases relate to Ipratropium Bromide.[5] Ipratropium Bromide is the generic version of Atrovent, a branded drug marketed by Roxane's sister company (BIPI). Roxane launched the first generic Ipratropium Bromide product in June 1996, three months prior to the expiration of patent exclusivity for Atrovent. In preparation for the launch of Ipratropium Bromide, Roxane hired a consultant named Mark Pope, who previously had worked for Dey and had experience marketing to the home health care market. Mr. Pope encouraged Roxane to set and report AWPs for its Ipratropium Bromide products at a high level in order to create an attractive spread and "entice" customers to convert from the brand name to the generic product as quickly as possible. *See* United States' Local Rule 56.1 Statement of Undisputed Material Facts as to the Roxane Defendants (MD #6293, Sub. #299) ¶¶ 45-51. At the time of launch, Roxane regarded competition with Dey as "the single most important factor that will influence the success of this product." Exhibit 21 to the Declaration of James J. Fauci Submitting Exhibits in Response to Boehringer Ingelheim Corporation and Boehringer Ingelheim Pharmaceuticals, Inc. Local Rule 56.1 Statement

[5] The damages from the combined impact on the Medicare program of the false Dey and Roxane AWPs for ipratropium bromide are over $1 billion. In contrast, total Medicaid damages are approximately $160 million for Dey, and $69 million for Roxane. The Medicare damages for Dey's albuterol sulfate are less than $600,000 dollars.

of Undisputed Facts In Support of Their Motion For Summary Judgment (MD #6412, Sub. #394) at p. ROX-TX-01342.

Dey was the second manufacturer to enter the generic Ipratropium Bromide market. Dey set its published AWPs for Ipratropium Bromide with a view toward competing with Roxane's product. *See* United States' Local Rule 56.1 Statement of Undisputed Material Facts as to Dey (MD #6296 Sub. #302) ¶¶ 136-142. Roxane and Dey actively competed for sales in the generic Ipratropium Bromide market from 1997 onwards, including by monitoring each other's respective AWPs and offering progressively larger rebates and other discounts resulting in increasingly lower sales prices (and increasingly larger spreads). *Id*. ¶¶ 144-145. By 2000, Dey and Roxane were selling the most popular package size of Ipratropium Bromide for approximately $12.00 and $11.00, respectively, yet each continued to report an AWP of $44.00.[6] Market share data indicates that by 2000, other competitors had entered the market but that Dey and Roxane continued to dominate the market for generic Ipratropium Bromide, with Dey assuming the leadership position.[7]

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[6] *See* Exhibit 19 to the Amended Declaration of George B. Henderson, II Submitting Exhibits in Support of Motion for Partial Summary Judgment (MD #6331, Sub. #336) (Declaration of Simon D. Platt) at Graph A9 and Summary A9 ; Exhibit 3 to the Declaration of James J. Fauci Submitting Exhibits in Support of Plaintiff's Motion for Partial Summary Judgment and in Opposition to the Roxane Defendants' Motion For Partial Summary Judgment (MD #6306, Sub. #310) (this exhibit was filed under seal) (Declaration of Simon D. Platt) at Graph A1 and Summary A1.

[7] *See* Exhibit 270B to Declaration of Sarah L. Reid in Support of Dey's Opposition To Plaintiffs' Motion for Partial Summary Judgment (MD #6426, Sub. #406) (expert report of Mark

D. The Cases Involve Similar and Overlapping Proof of Causation and Damages

As noted above, the United States has calculated Medicare damages for Ipratropium Bromide (against both Dey and the Roxane Defendants) and Albuterol Sulfate (against Dey only). For each of these multi-source drugs, Medicare reimbursement was made for all versions of the drug under a common Health Care Procedures Coding System ("HCPCS") code number, and the Medicare allowable amount was determined by four Durable Medical Equipment Regional Carriers ("DMERCs")[8] in accordance with published regulations and instructions from the Centers for Medicare and Medicaid Services ("CMS"). *See* Declaration of Carolyn Helton (Exhibit 1 hereto) ("Helton Decl."), ¶¶ 8, 10,[9] as corrected by Second Declaration of Carolyn Helton (Exhibit 2 hereto); *see generally In re Pharm. Indus. Average Wholesale Price Litig.*, 491 F. Supp. 2d 20, 34, 72-75, 98-100 (D. Mass. 2007). Throughout the relevant time frame, the Medicare reimbursement formula was based in part on the median AWP of all generic

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G. Duggan, P.h.D) at p. 130; Exhibit 96 to the Declaration of George B. Henderson, II Submitting Exhibits in Support of Motion for Partial Summary Judgment (MD #6298, Sub. #303), Table 36rev.

[8] From 1993 through 2003, the four DMERCs were designated to process claims for durable medical equipment. *See* 42 C.F.R. § 421.210 (amended 2005).

[9] The Helton declaration was also filed as Exhibit 3 to the Declaration of George B. Henderson, II Submitting Common Exhibits in Support of Motions for Partial Summary Judgment (MD #6310, Sub. #308). The Second Helton Declaration corrects minor mathematical errors in paragraph 40 of the first declaration.

forms of a drug.[10] *See* Helton Decl., ¶¶ 9, 13. The DMERCs determined the median AWPs for Ipratropium Bromide and Albuterol Sulfate by creating quarterly pricing arrays for each drug, identifying the relevant NDCs and their corresponding AWPs, and then selecting the median price. *Id.*, ¶¶ 9-11, 17-24. As a result, proving causation and damages to Medicare in both the Dey and Roxane cases implicates the same reimbursement formula, and will require testimony from the same DMERC witnesses.

For Ipratropium Bromide, which accounts for the majority of the United States' calculated damages in each case, proving causation and damages to Medicare will involve the exact same DMERC pricing array documents in both cases. These arrays include both Dey and Roxane AWPs and were used by the DMERCs to set the allowed reimbursement for Ipratropium Bromide each quarter. *Id.*, ¶¶ 21-23, Exhibit C. Moreover, because the allowed reimbursement generally was set as the median of all reported generic AWPs, the submission of false prices by multiple manufacturers combined to shift the median AWP and thereby increase the allowed reimbursement for all providers. Therefore, calculating the Medicare overpayment for Ipratropium Bromide caused by either Dey and the Roxane Defendants by necessity implicates evidence of *both* companies' pricing conduct to

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[10] Prior to November 1998, the Medicare allowed amount for multi-source drugs was set at the lower of the estimated acquisition cost or 100% of the median AWP for all sources of the generic form of the drug. 42 C.F.R. § 405.517 (1998) (amended 1998, 2004); 56 Fed. Reg. 59502-01, 59621 (Nov. 25, 1991). From November 1998 until 2003, the Medicare allowed amount for multi-source drugs was set at the lower of 95% of the median of all generic AWPs or the lowest AWP of the brand name forms of the drug. Section 4556 of the Balanced Budget Act of 1997, Pub. L. 105-33, 111 Stat. 462-463 (1997), codified at 42 U.S.C. §1395u(o)(1); 63 Fed. Reg. 58,814, 58905 (Nov. 2, 1998) (amending 42 C.F.R. § 405.517).

determine the actual effect their pricing conduct had on the median AWP and Medicare's allowed reimbursement.

Proof of causation and damages to state Medicaid programs will also overlap considerably. Establishing that Dey and the Roxane Defendants' price reporting caused state Medicaid programs to pay excess reimbursement will require evidence of how each program reimbursed for drugs including the role AWPs and Wholesale Acquisition Costs ("WACs") played in setting reimbursement. This evidence will be substantially the same in both cases, as each state Medicaid program reimbursed for drugs according to a reimbursement formula set out in a single State Plan approved by CMS. *See Massachusetts v. Mylan Labs.*, 608 F. Supp. 2d 127, 131-32 (D. Mass. 2008). The state plan documents themselves, as well as any testimony from state Medicaid officials further explaining the state's reimbursement methodology, are relevant to both cases.

E. Dey and the Roxane Defendants Are Likely To Rely on Similar Witnesses and Evidence At Trial

In the likely event that Dey and/or the Roxane Defendants pursue defenses focusing on the government's actions and/or inaction in either setting reimbursement or allegedly approving the defendants' reported AWPs, those defenses are likely to be based on substantially similar factual records involving many common witnesses and documents. Initially, Dey and the Roxane Defendants have pursued discovery against strikingly similar groups of federal employees. In its Second Supplemental Initial Disclosures served on December 15, 2008 (Exhibit 3 hereto), Dey identifies 114 current

and former employees of the federal government as likely to possess information that Dey might use to support its defenses.[11] Roxane incorporated each of these witnesses by reference into its Supplemental Initial Disclosures served January 12, 2009, and Roxane identified an additional 16 federal witnesses. Exhibit 4 hereto. A total of 38 federal employees have been deposed in the federal *Ven-a-Care* cases to date. Of these, Dey and the Roxane Defendants jointly participated in the depositions of 33 employees, and Dey participated in five federal employee depositions which Roxane did not attend. Of the 16 federal witnesses identified by Roxane but not Dey, none has been deposed.[12]

In addition, Dey and the Roxane Defendants are likely to rely upon many of the same documents in presenting their defenses. For example, expert witnesses proffered by Dey and the Roxane Defendants have relied upon reports prepared by the HHS Office of Inspector General (the "OIG Reports") as evidence that the United States "knew" that AWPs were inflated both generally and for the specific drugs at issue in this litigation. The OIG Reports relied upon by Dey and the Roxane defendants are substantially the same; for example, 23 of the 28 OIG reports referenced by one of Dey's experts (Professor David Bradford) are also referenced by one of Roxane's experts (Professor

[11] The vast majority of these employees are identified as working or having worked for either CMS or the Department of Health and Human Services, Office of Evaluation and Inspections ("OEI").

[12] There is even greater overlap among state Medicaid officials. Dey identified 126 current or former employees of state Medicaid agencies in its Second Supplemental Initial Disclosures. Each of these was incorporated by Roxane in its Supplemental Initial Disclosures, and Roxane did not identify any new state Medicaid officials.

Fiona Scott Morton). Likewise, experts for both Dey and the Roxane Defendants cite reports prepared by Myers and Stauffer as evidence that state Medicaid programs were on notice that the costs of dispensing drugs exceeded the programs' allowed dispensing fees.[13] Of the 27 Myers & Stauffer dispensing cost reports referenced by Professor Bradford (retained by Dey), 26 are also referenced by Professor Scott-Morton (retained by the Roxane Defendants).

II. ARGUMENT

A. The Court Has Broad Discretion to Consolidate the Cases for Trial

When considering a motion to consolidate pursuant to Fed. R. Civ. P. 42, "the threshold issue is whether the two proceedings involve a common party and common issues of fact or law." *See Cruickshank v. Clean Seas Co*., 402 F. Supp. 2d 328, 341 (D. Mass. 2005) (citing *Seguro de Servicio de Saludy v. McAuto Sys*., 878 F.2d 5, 8 (1st Cir. 1989)). "Once this determination is made, the trial court has broad discretion in weighing the costs and benefits of consolidation to decide whether that procedure is appropriate." *Id*. In considering the costs and benefits of consolidation, it is appropriate to consider and weigh the convenience or inconvenience to the parties, the judicial economy, the savings in time, effort or expense and any confusion, delay or prejudice that might result from consolidation. *See Gilliam v. Fidelity Mgmt. & Research Co.*, 2005 WL 1288105, *1 (D.

[13] The United States believes this "government knowledge" evidence is irrelevant, particularly in light of the recent decision in *In re Pharm. Indus. Average Wholesale Price Litig.*, – F.3d – (1st Cir. 2009), 2009 WL 3019691, Sept. 23, 2009.

Mass. 2005). A motion for consolidation will usually be granted unless the party opposing it can show demonstrable prejudice. *See Storlazzi v. Bakey*, 68 F.3d 455 (1st Cir. 1996). It is not necessary that the issues of fact and law be identical. *Cruickshank v. Clean Seas Co.*, 402 F. Supp. 2d at 341, citing *Tingley Sys., Inc. v. CSC Consulting, Inc.*, 152 F. Supp. 2d 95, 102 (D. Mass. 2001). Indeed, "[c]ommon questions of law and fact do not have to predominate. All that is required is that the district court find they exist and that consolidation will prove beneficial." 8 *Moore's Federal Practice* § 42.10[1][a] (Mathew Bender 3d ed.); *see Hendrix v. Raybestos-Manhattan, Inc.*, 776 F.2d 1492, 1495-1497 (11th Cir. 1985).

B. Consolidation Is Appropriate Because the Cases Involve a Common Party and Many Common Questions of Fact or Law

The United States is the plaintiff against Dey and the Roxane Defendants.[14] The cases involve a range of common questions of fact or law including, among others, whether defendants' reported AWPs were "false" and whether the reported AWPs caused the Medicare and Medicaid programs to pay inflated reimbursement. *See Ex Parte Novartis Pharm. Corp.*, 991 So. 2d 1263, 1275 (Ala. 2008) (denying request to vacate consolidation of AWP cases against Novartis Pharmaceuticals Corporation and GlaxoSmithKline; holding that common questions of fact or law existed including whether defendants had a duty to report accurate prices).

[14] The lawsuits originated as *qui tam* complaints filed by the same relator, Ven-A-Care of the Florida Keys, Inc.

With regard to Medicare, there is one common reimbursement methodology equally applicable to both cases. *See* footnote 10, *supra*. The details of this reimbursement methodology, as well as whether Medicare was aware and approved of defendants' price reporting, present common questions of fact and law. The same is true for Medicaid. Although the details of reimbursement methodologies differ from state to state, each program operated pursuant to the same federal regulations, including that "a state Medicaid program's payment for a drug may not exceed the 'estimated acquisition cost' of the drug, plus a reasonable dispensing fee, where the 'estimated acquisition cost' (EAC) is defined as 'the agency's best estimate of the price generally and currently paid by providers for a drug marketed or sold by a particular manufacturer . . . .'" *Massachusetts v. Mylan Labs.*, 608 F. Supp. 2d 127, 131-32 (D. Mass. 2008) (quoting 42 C.F.R. § 477.301 (2006)). The specifics of each state's reimbursement methodology, as well as the meaning of the Estimated Acquisition Cost and other federal regulations, are common questions that apply equally in the Dey and Roxane cases.

C. Consolidation Will Serve the Interests of Judicial Economy and Avoid Inconsistent Results

The cases against Dey and the Roxane defendants are likely to be both complex and time consuming. However, due to the extensive similarities between the cases, the burden on the parties and the Court will be significantly lessened by consolidating the cases for trial purposes. The government's evidence concerning the state Medicaid programs, including state and federal government witnesses, experts, and supporting

exhibits, will be substantially the same as to the Dey and Roxane defendants, with the only difference being the results of the government's damages calculations. The government's evidence concerning the Medicare program will likewise be substantially the same as regards both defendants. The United States expects the evidence presented by the defendants will overlap significantly.

Consolidation is particularly appropriate here because the United States will prove at trial that, in the case of Ipratropium Bromide, Dey and Roxane each legally caused a single injury to the Medicare program based on the combined impact of their price reporting on Medicare's allowable reimbursement amount. Therefore, proving damages in either case will of necessity require evidence of both companies' price reporting and both companies' impact on the Medicare program. As noted above, the Medicare reimbursement allowed amount was set at the lower of the median AWP of all generic forms of a drug or the lowest brand name AWP. As a result, fraudulent price reporting by multiple companies may dramatically impact Medicare spending, even when the impact caused by any one manufacturer appears negligible in isolation.

For example, in the fourth quarter of 1998, an array used by one of the DMERCs to calculate the allowable amount for Ipratropium Bromide included six generic AWPs, three of which were reported by Roxane and three of which were reported by Dey. *See*

Helton Decl., ¶¶ 22-24. The reported AWPs, along with alternative AWPs for the Dey and Roxane Products, are shown on the table below.[15]

Firm	NDC	Original AWP	Alternative Dey AWP	Alternative Roxane AWP	Alternative Dey & Roxane AWP
Compumed[16]		3.22	3.22	3.22	3.22
Dey	49502-0685-03	3.53	1.64	3.53	1.64
Dey	49502-0685-60	3.52	1.64	3.52	1.64
Roxane	00054-8402-11	3.52	3.52	1.70	1.70
Roxane	00054-8402-13	3.52	3.52	1.73	1.73
Roxane	00054-8402-21	3.52	3.52	1.74	1.74
	Median	3.52	3.37	2.48	1.72
	Allowable	$3.34	$3.20	$2.36	$1.63

The median of the reported generic AWPs was $3.52, which resulted in an allowed amount of $3.34 (i.e., $3.52 x 95%). *Id*. Substituting alternative AWPs for both the Dey and Roxane products reduces the median to $1.72, and the allowed amount to $1.63. *Id.* The difference between $3.34 and $1.63 (i.e., $1.71) represents the per unit overpayment that would have occurred if both Dey and Roxane's AWPs were found to be improperly inflated by the assumed amounts. Second Helton Decl. ¶ 2. In contrast, if one were to

[15] The alternative AWPs are based on the analyses of the United States' damages expert, Dr. Mark Duggan.

[16] Compumed was another manufacturer who sold the generic ipratropium bromide product.

determine the effect separately for the two companies, the reduction would be $0.14 for Dey (the difference between $3.34 and $3.20) and $0.98 for Roxane (the difference between $3.34 and $2.36). *Id*. The sum of the separate impacts is $1.12. It is clear that calculating the effect separately for each company would not reflect the true loss to the Medicare program resulting from the conduct of the two companies. *Id*.

The United States expects to prove at trial that Dey and Roxane are each legal causes of the combined impact their price reporting had on Medicare spending for Ipratropium Bromide. Causation under the False Claims Act generally involves application of common-law tort concepts, *see United States ex rel. Franklin v. Parke-Davis,* 2003 WL 2048255, * 4 (D. Mass. 2003), which "recognize that concurrent forces may bring about a single harm." *See Shyface v. Secretary, Health and Human Servs.*, 165 F.3d 1344, 1352 (C.A. Fed. 1999); (citing Restatement (Second) of Torts, §§ 431, 433(b)); *Comdyne I, Inc. v. Corbin*, 908 F.2d 1142, 1151 (3rd Cir. 1990) ("[W]here a harm is produced by concurrent acts, each act is the cause of the harm if it was a material element or 'substantial factor' in bringing the harm about") (internal citation omitted).[17]

Because the false price reporting of Dey and Roxane combined to create a single impact on the Medicare program, consolidation is appropriate, not only because the evidence of the combined impact is the same as regards both defendants, but also because

[17] *See also Schipani v. McLeod*, 541 F.3d 158, 163 (2nd Cir. 2008) (recognizing "that not every injury has only one cause. Thus, when multiple tortfeasors act concurrently or in concert to promote a single injury, they may be jointly and severally liable.").

a consolidated trial will avoid inconsistent results. *See International Paving Sys., Inc. v. Van Tulco, Inc.*, 806 F. Supp. 17, 22 (E.D.N.Y. 1992) (consolidating cases where conflicting results could occur if not consolidated).

Consolidation is appropriate regardless of whether the Roxane is deemed liable for false pricing as regards its Ipratropium Bromide NovaPlus® products. The discussion above applies whether or not Roxane is liable for its pricing of the NovaPlus products, because there are a number of quarters when the NovaPlus products were not in the arrays, but the Dey products and the other Roxane products were in the arrays. Moreover, as recognized by Dey, when the NovaPlus products were in the arrays, "the pricing and categorization of Roxane's NovaPlus affects the damages alleged to have been caused by Dey in one of the United States' damage models." Dey's Motion for Leave to Participate in the Depositions of Carolyn Helton and Robin Kreush Stone to the Extent This Court Grants Roxane's Expedited Motion for Leave to Depose Carolyn Helton and Robin Kreush Stone (MD #6384, Sub. #368) at p. 2. This is because, when the government's expert substitutes alternative AWPs for the published Red Book NovaPlus AWPs, the NovaPlus prices are determinative of the allowed amount calculation and thus become the sole cause of the resulting loss to the Medicare program – eliminating any causal impact of Dey's false prices. In any scenario, consolidation is appropriate to ensure consistency in the outcomes.

C. Defendants Cannot Demonstrate Any Prejudice That Will Result From Consolidation

Neither Dey nor Roxane can show that any meaningful prejudice would result from consolidation. Moreover, in evaluating the potential for prejudice, the Court should consider "the extent to which the risks of prejudice and confusion that might attend a consolidated trial can be alleviated by utilizing cautionary instructions to the jury during the trial and controlling the manner in which the . . . claims are submitted to the jury for deliberation." *Hendrix v. Raybestos-Manhattan, Inc.*, 776 F.2d at 1494; *see Carpenter v. GAF Corp.*, 1994 WL 47781 *2 (unpublished), 16 F.3d 1218 (table) (6th Cir. 1994) (consolidation of cases creates no prejudicial impression on jury regarding extensiveness of damages, where defendants had opportunity to cross-examine damages experts); *Gonzalez-Quiles v. Cooperativa De Ahorro Y Credito De Isabela*, 250 F.R.D. 91, 94 (D. P.R. 2007). In the final analysis, any claim of prejudice that the defendants might raise is far outweighed by the advantages of consolidation.

CONCLUSION

For the foregoing reasons, the Court should grant the United States' motion to consolidate these cases for trial.

Dated: October 13, 2009

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that I have this day caused an electronic copy of the above document and accompanying exhibits to be served on all counsel of record via electronic service pursuant to Paragraph 11 of Case Management Order No. 2 by sending a copy to LexisNexis File & Serve for posting and notification to all parties.

/s/ George B. Henderson, II
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Dated: October 13, 2009